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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,812	09/01/2000	Haig H. Kazazian JR.	53893-5006-02	6101

23973 7590 10/09/2007

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/653,812	KAZAZIAN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,36-44,46,47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,36-44,46,47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 29, 2007 has been entered. Claims 34 and 36-44 have been amended.

Accordingly, Claims 34, 36-44, 46, 47, and 49 remain pending.

The remarks filed March 27, 2007 (hereinafter referred to as "the response") are considered herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/07 has been entered.

The remarks filed March 27, 2007 are considered herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36-44, 46, 47, and 49 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the Office Actions of 12/17/01, 9/22/04, 6/2/05, 9/21/06 and the Advisory Action of 12/27/05, and for the reasons discussed herein, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a transgenic mouse comprising a specific retrotransposon, as well as a sperm cell obtained from a male transgenic mouse comprising said specific retrotransposon. The claims cover transgenic mice having any gene inserted as well as those having any gene disrupted.

Although the claims have been amended to recite a disease model, the specification fails to disclose any disease model, let alone the huge variety of disease models that the claims now cover. The specification does not describe or enable an appropriate disease model as it does not describe an appropriate genetic modification and the resulting phenotype of a transgenic mouse comprising the retrotransposon recited in the claims. As noted at page 5, paragraph 3 of the Office Action of 9/22/04, since the specification does not disclose a transgenic mouse having a disease phenotype, the skilled artisan would not know how to use the claimed transgenic mouse.

At pages 6-7 of the response, Applicants assert that the specification provides many uses for the claimed transgenic mouse and that all these uses are enabled.

At page 6 of the response, Applicants point to the specification at page 16, beginning at line 7, and assert that the cited section describes a use for the transgenic animal "for random insertional mutagenesis in the animal." It does not. The cited section only refers to a use for the **retrotransposon element**, not for the claimed transgenic mouse. The cited section does not mention a transgenic animal at all. Nowhere does the specification describe how **an animal** can be used to effect random insertional mutagenesis in an animal. Such a use does not make sense. Moreover, the paragraph Applicants cite only describes a use for the L1 retrotransposon element, not an animal, stating that "these retrotransposons may be used for random insertional mutagenesis" (page 16, lines 19-20). The cited paragraph does not contemplate a use for the claimed transgenic mouse. These arguments have already been addressed in the Office Action of June 2, 2005 (see pages 3-5).

At page 6 of the response, Applicants point to the specification at page 20, beginning at line 24, and assert that the cited section discloses the use of a transgenic animal comprising a DNAc molecule

useful for generating mutations in a cell and for the generation of transposon mutagens. Again, only the DNA molecule is "useful for generating mutations in a cell and for the generation of transposon mutagens," not the animal. The animal cannot be used to generate mutations in the cell or to generate transposon mutagens. The cited paragraph states that "[e]ngineered L1 elements can also be used as transposon mutagens." Obviously, the claimed **transgenic mice** cannot be used for the generation of transposon mutagens. The cited paragraph also states that the DNAs of the invention are useful for generating transgenic animals having insertional mutations, contrary to Applicants present assertion that the **animals** would be used to to generate mutations. There is nothing in the specification that suggests that transgenic mice can be used to actually generate mutations. The cited paragraph does not contemplate a use for the claimed transgenic mouse. These arguments have already been addressed in the Office Action of June 2, 2005 (see pages 3-5).

At page 6 of the response, Applicants point to the specification at page 27, line 22, and assert that the specification describes "*using* transgenic mice comprising a DNAc molecule for generating high frequency mutation" (emphasis original). Of course, it is the DNAc molecule that is used to generate high frequency mutations, not the transgenic mouse. The cited paragraph only describes how to make transgenic mice of the invention. There is nothing in the cited paragraph that refers to a use for the claimed transgenic mice. These arguments have already been addressed in the Office Action of June 2, 2005 (see pages 3-5).

At pages 6-7 of the response, Applicants point to the specification at page 28, beginning at line 4, and assert that "this high frequency mutation can be *used* to provide mutations in a variety of genes, including genes which provide resistance or susceptibility to tumor development" (emphasis original). Applicants conclude that the skilled artisan could "*use* the transgenic mammal and the sperm presently claimed to illuminate the function of various genes in which the DNAc molecule integrated" (emphasis original). The cited paragraph does not contemplate a use for the claimed transgenic mice, but rather

states that "promoter traps or enhancer traps in somatic cells may be used to provide mutations in a variety of genes, including, but not limited to genes which provide susceptibility or resistance to tumor development in various cell types." Indeed, the transgenic mouse described in the specification (page 27, line 22 to page 28, line 3) would have many mutations within a single mouse, including the initial germline genetic modification, followed by many somatic cell modifications, so that the resulting mouse would be a mosaic animal having different mutations in different cells and tissues. Nowhere does the specification teach how to use such a mouse to identify genes which provide resistance or susceptibility to tumor development. The cited paragraph does not teach how to use the claimed transgenic mouse to identify genes which provide susceptibility or resistance to tumor development in various cell types and furthermore does not teach how to use the claimed transgenic mouse "to illuminate the function of various genes in which the DNAc molecule integrated," as Applicants allege. These arguments have already been addressed in the Office Action of June 2, 2005 (see pages 3-5).

Thus, the rejection under 35 U.S.C. 112, first paragraph is maintained, for reasons of record.

Conclusion

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632